

LEVERAGING CDMOS IN PHARMA'S DRIVE TOWARD NET ZERO

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The push to reduce carbon emissions across some of the most energy-intensive industries has created new complexities for many companies. For the pharmaceutical industry, working toward net zero can be particularly complicated, as it means targeting improvements within a manufacturing paradigm that is largely outsourced to contract development and manufacturing organizations (CDMOs).

Finding a CDMO partner committed to working toward net zero will be crucial for companies trying to stay ahead of emissions requirements. Ajinomoto Bio-Pharma Services, a fully integrated CDMO with sites in Belgium, the U.S., Japan, and India, has established an innovative, effective approach to emissions mitigation that incorporates pioneering technologies, cross-functional teams, and ambitious internal emissions goals to help customers reach carbon neutrality.

Addressing Pharma's Role in Global Emissions

The pharmaceutical industry is a significant contributor to GHG emissions globally – a study published in 2019 in the *Journal of Cleaner Production* found that the 2015 emissions rates for the pharmaceutical industry outstripped those of automotive production in the same year. The study, which also analyzed the GHG emissions of the top 15 largest global pharmaceutical companies, found that emissions varied greatly between players with comparable revenue, with some companies producing as much as five times the emissions of their competitors. This variability, according to the authors, signaled “a very disparate set of environmental practices within the industry.”

More recently, many pharmaceutical companies have begun to prioritize environmental stewardship

as part of their overarching manufacturing strategy. This planning often revolves around vetting a company's outsourcing partners, which typically represent the lion's share of a manufacturing workflow for a given application. These considerations are particularly important for companies operating in European nations, many of which have enacted proactive legislation targeting emissions and which are bound by the EU's Green Deal, pledging to make the EU the first climate-neutral continent by 2050.

The challenges inherent to “greening” manufacturing in the pharmaceutical space are further complicated by a rigorous regulatory environment. Equipment and processes cannot be updated without undergoing regulatory vetting and validation; for many companies, particularly those with mature products or processes, the prospect of transitioning to cleaner manufacturing can be difficult to justify in the short term. But as the EU Emissions Trading System (EU-ETS), as well as the pledges made by many major pharmaceutical companies, begin to take effect, the pressure to transition to greener manufacturing is mounting for companies averse to change. Focusing on partnering with a CDMO able to evaluate an existing process for opportunities to cut emissions can help ameliorate the burden of this undertaking; doing so before it is required by law or regulation can further help companies avoid compounding consequences and a rush to comply.

Identifying Incremental Solutions to Achieve Net Zero

Commitments to net zero are likely to become even stronger in the coming years, as more recognition surrounding the impacts of – and contributors to – emissions drive more systemic change. The UN Climate Change Conference in Glasgow (COP26) held in 2021 affirmed the UN's commitment to achieving net zero by 2050; likewise, U.S. President Joe Biden, who spurred the U.S. to rejoin the Paris Agreement, launched a whole-of-government process, organized through the National Climate Task Force, to achieve a 50-52 percent reduction from 2005 levels in economy-wide net greenhouse gas pollution by 2030. Other large nations have ventured to commit to reducing GHG emissions. For example, in 2020, Chinese president Xi Jinping announced China would target carbon neutrality before 2060. Similarly, India has pledged to achieve net zero emissions by 2070.

While 2050, 2060, or 2070 may seem like far-flung targets for companies maneuvering to achieve market acceptance at an accelerated pace, the pitfalls of failing to scale with greener manufacturing in mind are likely to incur penalties for them in the coming decade. Identifying the appropriate manufacturing approach for both quality and environmental impact will require partnering with a CDMO that has done the requisite work to pioneer solutions across a range of modalities.

Implementing Sustainability Practices

There are multiple ways in which CDMOs can immediately work toward implementing initiatives that will bring the industry closer to a more sustainable, greener future. At Aji Bio-Pharma, cross-functional teams have developed a holistic vision that addresses its climate objectives over three scopes following guidance identified by the Greenhouse Gas Protocol, a comprehensive, standardized framework for measuring and managing GHG emissions from private and public sector operations. This GHG Protocol classifies a company's emissions under three scopes: Scope 1, which includes direct emissions from owned or controlled sources; Scope 2, which covers indirect emissions from the generation of purchased energy; and Scope 3, which includes all indirect emissions not covered by Scope 2 that may occur across a company's value chain, including upstream and downstream emissions.

To address the emissions covered under each scope, Aji Bio-Pharma is employing energy-improving projects across its business units, coupled with initiatives bundled as “diversify & electrify”. For instance via purchase policy to hybrid installations capable to work on non-fossil fuels and switching to highly efficient heat pumps. Complementary to the shift to 100 percent green electricity for all of its Belgian sites, these investments resulted in an overall emissions decrease of 20 percent for 2021. It is on track to exceed the FY25 GHG objective (**scopes 1 & 2**).

The largest contributing factor is the upstream and downstream emissions, **scope 3**. To make incremental steps, Aji Bio-Pharma launched partnerships with third parties and its customers. Reducing waste through engagement with world-leading companies, valorizing waste streams, and regenerating solvents, to name a few, are making steps toward circular usage of material streams.

Eco Passport – Adopting New Technologies for More Efficient, Less Wasteful Drug Manufacturing

One of Aji Bio-Pharma's most promising tools when it comes to achieving net zero targets is its Aji Bio-Pharma Eco Passport. This tool, used as the basis for identifying continuous process improvements, can also model scenarios during the Request for Proposal (RFP) phase, accurately reporting the positive climate impact of alternative scenarios. By calculating carbon footprint down to the process step level, Aji's Eco Passport can help companies achieve greater insight into the incremental improvements that can serve as stepping-stones to carbon neutrality – calculations comparing the use of virgin solvent vs. regenerated solvent, for example, can help companies understand the cost and benefits of enacting a single change to a manufacturing paradigm.

For a new product inquiry, Aji Bio-Pharma can use the Eco Passport to identify alternate solvents, manufacturing technologies, or chemistries to improve the footprint of a manufacturing process. Much of its approach centers on continuous manufacturing, as Aji Bio-Pharma's in-house researchers possess a wealth of expertise in transitioning batch manufacturing to continuous flow processes. Even more nascent solutions such as photo flow, which derives energy from light rather than electricity or gas, have been explored as part of its greater commitment to net zero.

Ultimately, reducing its CO2 footprint, downsizing energy consumption, and limiting waste are all core facets of Aji Bio-Pharma's sustainability commitment and initiatives. In 2020, the CDMO reviewed and revised its environmental goals to reflect the longer-term greenhouse gas reduction requirement to meet the Paris Climate Agreement. With its energy and greenhouse gas targets, Aji Bio-Pharma aims to reduce its CO2 emissions intensity to below 50 percent in 2030 and to become carbon neutral in 2050. Tailored waste disposal concepts are in place at each Aji Bio-Pharma manufacturing site, ensuring an efficient, environmentally sound treatment of wastes. Additionally, as part of its Sustainability Entrepreneurship program, it also launched several objectives focusing on reducing use of water sources and even use of alternative water sources.

Selecting the Right CDMO Partner for Sustainability

Choosing a partner to carry your product from conception to market is a commitment for the future. It's important to consider forward-thinking factors outside of price, availability, and service. The environmental considerations that accompany a manufacturing strategy have become increasingly important in the face of additional calls to address pollution and sustainability practices globally. With its broad spectrum of differentiating technologies, including continuous flow, enzymatic chemistry, photo flow, and others, Aji Bio-Pharma possesses the capabilities and expertise to help customers identify and implement greener, more efficient technologies and processes. Facility features like its continuous flow manufacturing unit help provide supporting data to validate lower energy usage, increased safety, less solvent usage, and higher yield for many applications.

About Ajinomoto Bio-Pharma Services

Ajinomoto Bio-Pharma Services is a fully integrated contract development and manufacturing organization with sites in Belgium, United States, Japan, and India, providing support across gene therapy, APIs, and both large and small molecule manufacturing. Ajinomoto Bio-Pharma Services offers a broad range of innovative platforms and capabilities for pre-clinical and pilot programs to commercial quantities, including high potency APIs (HPAPI), continuous flow manufacturing, oligonucleotide synthesis, biocatalysis, Corynex® protein expression technology, antibody drug conjugations (ADC) and more. Ajinomoto Bio-Pharma Services is dedicated to providing a high level of quality and service to meet our client's needs. Learn more: www.AjiBio-Pharma.com